K051722

510(k) Summary

NOV 1 8 2005

Submitted by:	Baxter Healthcare Corp. One Baxter Way Westlake Village, CA 91362 805-372-3000
Contact Person:	Brian Bishop, Sr. Manager, Global Regulatory Affairs Biologics
Date Prepared:	24 June 2005
Proprietary Name:	TricOs T
Common Name:	Bone Void Filler
Classification Name:	Resorbable Calcium Salt Bone Void Filler (21 CFR §888.3045)
Predicate Device:	MBCP BIOMATLANTE 510(k) K032268 Collagraft Strip Bone Graft Matrix NeuColl, Inc. 510(k) K000122 Allomatrix Putty Wright Medical Technology, Inc. 510(k) K020895 TCP Putty Stryker Biotech 510(k) K041421 JAX-tcp Smith & Nephew, Inc. 510(k) K033552

Description of the Device: TricOs T is a resorbable bone substitute that is replaced over time by newly formed bone. TricOs T consists of an inorganic calcium phosphate scaffold (HA/TCP granules) combined with a heterologous

human fibrin matrix. The fibrin matrix acts as a 3D matrix and enhances the handling of the product by making it moldable and allows it to hold its shape.

Intended Use of the Device: TricOs T is indicated for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated for surgically created osseous defects or osseous defects resulting from traumatic injury. TricOs T is a bone void filler without initial mechanical properties, therefore rigid fixation techniques may often be recommended.

TricOs T is intended to be packed into bony voids or gaps of the skeletal system (i.e. the extremities, spine, and pelvis). Following placement in the bony void or gap, TricOs T is resorbed and replaced with bone during the healing process.

Fibrin matrix without the HA/TCP granules is not indicated for use as a bone void filler.

Technological Characteristics: TricOs T has similar characteristics to the predicate devices listed above. The product characteristics and design and chemical safety are in conformance with the ASTM standard for hydroxyapatite for implantation, F1185.

Nonclinical tests: TricOs T has been tested in *in vivo* and *in vitro* studies that document safety and effectiveness equivalent to that of the predicate devices.

Substantial Equivalence Information: The intended use, composition, biocompatibility and select performance properties of TricOs T are substantially equivalent to commercially available predicate bone void filler products. The product is adequately supported by the substantial equivalence information, materials data, and testing results provided or referenced to in the Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 8 2005

Brian L. Bishop, RAC
Associate Director
Global Regulatory Affairs, Biologics
Baxter Healthcare Corporation
One Baxter Way
Westlake Village, California 91362

Re: K051722
Trade/Device Name: TricOs T Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: November 1, 2005
Received: November 2, 2005

Dear Mr. Bishop:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number:

Device Name: TricOs T, Bone Void Filler

Indications For Use: TricOs T is indicated for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated for surgically created osseous defects or osseous defects resulting from traumatic injury. TricOs T is a bone void filler without initial mechanical properties, therefore rigid fixation techniques may often be recommended.

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Prescription Use
___X___
(Per 21 CFR §801.109)

OR

Over-The-Counter Use_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051722